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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/034,139 | 12/27/2001 | James Kelly Fox | G&C 130.40-US-01 | 1622 |
| 22462 | 7590 | 07/25/2005 | | |
| GATES & COOPER LLP HOWARD HUGHES CENTER 6701 CENTER DRIVE WEST, SUITE 1050 LOS ANGELES, CA 90045 | | | EXAMINER NATNITHITHADHA, NAVIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,139

Applicant(s)

FOX ET AL

Examiner

Navin Natnithithadha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-30,32 and 34-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-30,32 and 34-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02182005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 4, 6, 7, 10-13, 16, 23, 29, 32, 34, 35, 38-41, 44, and 51 have been amended. Claims 3, 5, 31, 33, and 57-110 have been cancelled. Claims 1, 2, 4, 6-30, 32, and 34-56 are pending.

Response to Arguments

2. The objection to claim 1 is WITHDRAWN in view of the Amendment filed 06 May 2005.

3. Applicants' arguments filed 06 May 2005 have been fully considered but they are not persuasive.

In regards to amended independent claims 1, 23, 29, and 51, the Applicants' traverses the Examiner's previous rejection because (see Applicants' Remarks, page 12 and 13):

"The portion of Say cited by the Examiner as a basis for the rejection of claims 5, 23, 33, and 51, column 51, lines 29-36, discusses an alarm system activated when the rate or acceleration of an increase or decrease in analyte level reaches or exceeds a threshold value. Say lacks any discussion about using a slope of a line fit to the series of physiological characteristic values that is calculated if a most recent of the series of physiological characteristic values meets or exceeds a particular criterion. Instead, Say teaches away from Applicants' invention because it teaches indicating a hyperglycemic or hypoglycemic condition is likely to occur simply when the rate or acceleration of increasing or decreasing analyte levels occur. Say contains no suggestion or motivation to modify this approach by making the calculation of a slope of a line fit to the series of physiological characteristic values conditional on the level of a most recent of the series of physiological characteristic values."

However, Say discloses that acceleration is the increase or decrease in the rate of change of the analyte/glucose level vs. time graph (see col. 51, lines 4-12 and lines 29-36). Based on basic engineering principles, one technique in determining acceleration is by calculating the slope of a curve on a graph (i.e. glucose level vs. time graph).

Therefore, the manner in which Say provides an "observable indication", i.e. alarm, is by determining if the increase or decrease in acceleration, i.e. slope, exceeds a qualifying range or threshold value (see col. 51, lines 29-36). Thus, the rejections for claims 1, 23, 29, and 51 are MAINTAINED. Since the rejections of the dependent claims were traversed for the same reasons, these rejections are also MAINTAINED.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 6-9, 11, 13-15, 23, 25, 27, 28-30, 34-37, 39, 41-43, 51-53, 55, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Say et al, US 6,175,752 B1.

In regards to claims 1, 2, 6, 8, 14, 15, 23, 28-30, 34, 36, 42, 43, 51, 52, and 56, Say teaches an analyte (physiological characteristic) monitor (see abstract) and method of monitoring analyte, specifically measuring the concentration of blood glucose. The analyte monitor comprising:

- a receiver (input device) 150 receiving a signal from a sensor 42;
- a processing circuit (processor) 109 analyzing the received signal;

wherein the processing circuit 109 repeatedly determining rate of change of analyte based on a series of sensor signals; and

wherein the processing circuit 109 provides an observable indicator 168 of certain conditions based on the level of analyte (see col. 50 line 11-31 and 52-65).

In addition, Say teaches determining an acceleration (slope) of an increase or decrease (increase or decrease slope) in the level of analyte reaches or exceeds a predetermined threshold value for hypoglycemic or hyperglycemic conditions (see col. 51, lines 29-36).

As to claims 7, 9, 25, 27, 35, 37, 53, and 55, Say teaches an indicator 168 and alarm system 156 in response to anticipated hypoglycemia (glucose crash or low glucose levels) 170 or anticipated hyperglycemia (high glucose levels) 172 (see col. 50, lines 59-65).

As to claims 11 and 39, Say teaches an indicator 168 and alarm system 156 in response to anticipated hypoglycemia (glucose crash or low glucose levels) 170 or anticipated hyperglycemia (high glucose levels) 172 (see col. 50, lines 59-65).

As to claims 13 and 41, Say teaches the alarm system 156 warns the patient of impending condition (hypoglycemia or hyperglycemia) when the rate or acceleration (slope) of an increase or decrease in analyte level reaches or exceeds a threshold value (see col. 51, lines 29-36).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 4, 16, 17, 19-22, 32, 44-46, and 48-50 are rejected under 35

U.S.C. 103(a) as being unpatentable over Say et al, US 6,175,752 B1, as applied to claims 1 and 29 above, and further in view of Mault et al, US 2003/0208113 A1.

As to claims 4, 16, 32, and 44, the claimed subject matter is a well-known function of fitting a curve to a series of values in a data stream. Mault teaches fitting a curve 342 to data by a computer, i.e. processing circuit, to a series of blood glucose measurements over a period of time (see fig. 12 and paragraph [0126]). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Say's processing circuit to include a "curve fitting" function in order to visually model the person's glycemic response.

As to claims 17 and 45, Say teaches the alarm system 156 warns the patient of impending hypoglycemia or impending hyperglycemia (see col. 51, lines 19-28). It is possible that these conditions may occur in the morning and, therefore, the alarm system 156 would warn the patient of impending morning hypoglycemia/hyperglycemia.

As to claims 19 and 46, Say teaches determining an acceleration (slope) of an increase or decrease (increase or decrease slope) in the level of analyte (see col. 51, lines 29-32) and averaging a series datapoints (see col. 51, lines 29-50). In addition, Mault teaches analyzing the curve for rise slope behavior and decay slope behavior in the data (see paragraph [0126]).

As to claims 20 and 48, Say teaches anticipating hypoglycemia or hyperglycemia in a period of time spanning a predetermined number of hours (see fig. 12). Any of

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these values on the curve in Figure 12 could be determined approximately three hours before an anticipated wakeup time.

As to claims 21, 22, 49, and 50, Say teaches exceeds predetermined threshold values for hypoglycemic or hyperglycemic conditions.

6. Claims 10, 12, 18, 26, 38, 40, 46, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al, US 6,175,752 B1, as applied to claims 1, 16, 23, 29, 44, 51 above, and further in view of Houben et al, US 6,572,542 B1.

As to claims 10, 12, 18, 26, 38, 40, 46, and 54, Say does not specifically teach the series of data corresponding to the level of analyte, or glucose, spans a time period of approximately ten, thirty, or sixty minutes. However, Houben teaches monitoring glucose in a span a time, which covers the specified time period claimed (see fig. 12). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Say's processing circuit to monitor a series of data in order to provide accurate warning to a hypoglycemic or hyperglycemic event.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Navin Natnithithadha
Patent Examiner
GAU 3736
19 July 2005


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